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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,762	12/28/2000	Kazuyuki Yanase	K0208.014	5214

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EXAMINER

SAYOC, EMMANUEL

ART UNIT PAPER NUMBER

3746

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,762

Applicant(s)

YANASE ET AL.

Examiner

Emmanuel Sayoc

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. This office action is in response to the amendments received on 6/25/2004. Claim prosecution is re-opened under the applicant's request for continued examination, 2/06/2004 paper 14. In making the below rejections and/or objections the examiner has considered and addressed each of the applicants arguments. Claims 4 and 5 have been cancelled. Claims 1-3, and 6-11 are emended and are pending.

Drawings

2. Proposed amendments to the drawings received 2/09/2004 are accepted. New Formal drawings are required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 3, and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136), and in further view of Ito (U.S. 5,063,025).

With respect to claims 1, and 6-8, Trull et al., in Figure 6, disclose a syringe gasket (70) wherein a peripheral side surface (80) of the gasket is in contact with an inner surface of the syringe barrel (60). A restriction (labeled by the examiner on Figure 6

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attached to the end of this office action) is provided, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered slant (also labeled by the examiner on Figure 6).

The Trull et al. differs from the claimed invention in that there is no disclosure of one or both of the peripheral side surfaces that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with polyethylene fluoride resin. Ito, in column 5 lines 1-7, discloses that a syringe gasket is commonly coated with a thermoplastic resin such as polyethylene or polypropylene (TEFLON). Such material is optimum in that it eliminates the need for a lubricant and serves as a protective coating for the gasket. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of polyethylene or polypropylene, in order to achieve optimum gasket lubrication, functionality, and protection within a syringe device.

With respect to claim 3, the Trull et al. apparatus comprises a tapered slant with a first and second plunger diameter. The examiner has labeled these embodiments on the marked up Figure 6.

The Trull et al. differs from the claimed invention in that there is no disclosure of the first and second diameter of the tapered slant having a difference between about .5mm and about 5mm. Furthermore, with respect to claims 6-8, there is no disclosure of the gasket's inner diameter, its height, its first diameter, or its second diameter. With respect to the specified gasket dimensions in the claim 3 and 6-8, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

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optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

6. Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Ito, as applied to claim 1, and in further view of Akaike et al. (U.S. 5,061,247).

Trull et al., as modified by Ito, set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al. device differs from the claimed invention in that there is no disclosure of the hardness of the gasket being between 55 to 60 (JIS hardness meter). Akaike et al., in column 5 lines 58-59, disclose, that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Ito, gasket by using a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device.

With respect to claims 9 and 10, a second tapered slant is formed between the peripheral side surface of the gasket that is in contact with an inner surface of the syringe barrel and the restriction. The gasket tightly closing the liquid is an obvious requirement for the syringe to pump fluid properly. A recitation with respect to the material intended to be worked upon by a claimed apparatus does not impose any structural limitations upon the claimed apparatus, which differentiates it from the prior art apparatus satisfying the structural limitations of the claims, as is the case here.

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7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., as modified by Ito, as applied to claims 1 or 9, and in further view of Higashikawa (U.S. 5,830,193).

Trull et al., as modified by Ito, set forth a device as described above, which is substantially analogous to the claimed invention. The Trull et al. device differs from the claimed invention in that there is no disclosure of the syringe including a lure lock.

Higashikawa in Figure 1a-1c teaches that lure lock mechanisms (37, 30, 22) have been especially common in medical syringes (21) for mounting needles (32). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the Trull et al., as modified by Ito, device by incorporating the lure locking mechanism, as taught by Higashikawa, in order to allow for needle mounting.

Response to Amendment

9. The amendment to the title is hereby acknowledged.
10. The objection to claim 11, is hereby withdrawn.

Response to Arguments

11. Applicant's arguments filed 6/25/2004 have been fully considered but they are not persuasive. The examiner has shown in the prior art that it was well known to coat syringe gaskets or plungers with polyethylene or polypropylene, as taught by Ito. The examiner withdraws the statement that the TEFLON coating alleviates the need for a lubricant, not that the examiner disagrees with the statement, but in order to concentrate

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on stated facts in the reference. The applicant claims that the combination of Trull et al. and Ito is improper on the grounds that the Ito device is directed to a syringe for liquid chromatography, and that the Ito device addresses fluid pumping difficulties other than that of injecting liquid into the human body such as leakage due to heat and pressure of sterilization. The combination is directed to applying a polyethylene or polypropylene, TEFLON, lamination on the plunger, as taught by Ito, onto the Trull et al. device. Ito teaches that this coating is intended to protect the plunger from any adverse effects of the pumped fluid. The applicant challenges the motivation of applying this teaching to the Trull et al. device stating that the coating is Ito is, intended for protecting against corrosive fluids, is not required in the normal use of the Trull et al. device. The examiner agrees on the fact that Ito teaches a protective polyethylene or polypropylene coating. The art of syringe pumping is such that one of ordinary skill in the art could have taken the Trull et al. and realize that the device can be used for pumping in a wide variety of applications, and fluids. Those fluids may be corrosive or not. The coating teaching combined with the Trull et al. device would not interfere with the intended use and it would make the device for versatile in handling a larger variety of fluids. In the apparatus claim, the applicant cannot rely solely on the intended use/particular application of the Trull et al. device. The examiner holds that the combination of Trull et al. and Ito, as outlined above it proper, in that it would have been obvious to one of ordinary skill, there is a distinctive improvement/motivation in the combination, and that the combination does not interfere with the cited application of the Trull et al. Device. The examiner holds that both references are within the field of the applicant's endeavor. Applicant's further amendments do not provide any further limiting patentable structure.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are cited to further show the state of the art with respect to gaskets for syringes.

U.S. Pat. 5, 688, 252 to Matsuda et al.

U.S. Pat. 5, 397, 313 to Gross

U.S. Pat. 4, 303, 070 to Ichikawa et al.

U.S. Pat. 4,474,071 to Marteau d' Autry – teaches a coating for protection.

The applicant is invited to note the tapered slants in the listed references.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Contact Information

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emmanuel Sayoc whose telephone number is (703) 305-0054. The examiner can normally be reached on M-F 8 A.M. - 6 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (703)308-2675. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Emmanuel Sayoc
Examiner
Art Unit 3746

ECS



**JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
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8/23/09